

## **APPARATUS FOR POSITIONING PROSTHETIC COMPONENT PRIOR TO CEMENT INJECTION**

### Reference to Related Applications

This is a continuation application of co-pending U.S. patent application Serial No. 09/396,576, filed September 15, 1999, which is a continuation of U.S. patent application Serial No. 09/029,457, filed March 5, 1998, now U.S. Patent No. 6,267,785, which is a U.S. national phase application of Patent Cooperation Treaty application Serial No. US97/01754, filed January 31, 1997, which claims priority of U.S. patent application Serial No. 08/595,277, filed February 2, 1996, the entire contents of each application being incorporated herein by reference.

### Field of the Invention

This invention relates generally to arthroplasty and, more particularly to devices and techniques for positioning a prosthesis prior to fixation through the injection of a bonding agent.

### Background of the Invention

In current joint repair situations, it is common practice to prepare host bone stock to receive an implant then, if satisfied with the physical correspondence, apply cement to the host, install the prosthesis, and stabilize the arrangement until curing. This approach has several disadvantages. Foremost among them arises from the unpredictable process of ensuring that, although the prosthesis may have been ideally placed prior to cementation, once the cement is applied, orientation may shift, resulting in a final configuration which is less than optimal.

A few approaches have been attempted to assist in making the positioning of the final implant more predictable. As discussed further in the detailed description herein, one such approach utilizes a centralizing plug inserted distally within the medullary canal, and from

which there extends a rod upon which a final implant including a corresponding central bore may be monorailed. The plug and rod are positioned in conjunction with a trial which also includes a central bore, which is then removed, the intramedullary cavity filled with cement and the final implant slid over the rod, displacing the cement as it is pushed down into position. Although this technique may assist in maintaining a side-to-side orientation prior to cementation, it does not address the simultaneous need for up-and-down and/or rotational stabilization. Additionally, as with current techniques, cement is applied to the host prior to the introduction of the final implant, leaving open the possibility that the final implant may be held in a position different from that associated with the trial, and may therefore result in an unacceptable misplacement as the cement cures.

Other approaches do reverse this order, and install the final implant prior to the injection of cement. The known approaches, however, utilize a highly specialized prosthetic device including centralizing protrusions and internal channels through which the cement is introduced. That is, in these systems, the prosthesis itself is used as the cement injector. Due to their requirement for a highly specialized final prosthetic element, such systems are incompatible with currently available implant devices, and therefore raise costs while reducing the options of the practitioner. In addition, they do not adequately address the need for simultaneously stabilizing multiple degrees of freedom prior and during cementation. As a further disadvantage, the systems which use the prosthesis as the cement injector tend to use the cement as a grout between the outer surface of the implant and the inner surface of the receiving cavity. It has been shown, however, that the chances of success are improved through the creation of a thicker cement "mantle," as opposed to a thin grout-type layer. The need remains, then, for a system whereby the prosthesis may be stabilized relative to multiple degrees of freedom prior to cementation, and, ideally, remain compatible with existing prosthetic components while forming a strong and stable bond to the host.

### Summary of the Invention

The present invention resides in apparatus and methods for maintaining the proper positioning of a prosthetic implant having proximal and distal ends within a prepared bone cavity during cement injection and curing. In contrast to prior-art systems the invention provides first stabilization means, implantable within the bone cavity, for minimizing lateral movement of the distal end of the implant, and second stabilization means, physically separate from the means for minimizing lateral movement of the distal end of the implant, for minimizing both the lateral movement of the proximal end of the implant and the rotational movement of the implant overall. In the preferred embodiment, the second stabilization means includes an apertured cap removably securable to the end of a bone having the prepared cavity through which the implant is inserted and held in place. This cap, which may either be entirely rigid or include a pliable membrane in the vicinity of the aperture, preferably further includes a first port associated with cement injection and a second port associated with cement over-pressurization. In an alternative embodiment, the second stabilization means includes a manually operated mechanism enabling the implant to be temporarily yet rigidly secured thereto in accordance with a desired orientation, preferably affording adjustments along multiple degrees of freedom prior to the rigid securement thereof.

### Brief Description of the Drawings

FIGURE 1A illustrates, in skeletal form, the first step of a prior-art implantation sequence involving host bed preparation;

FIGURE 1B depicts an intermediate step in the prior-art sequence wherein the cavity prepared according to Figure 1A is filled with cement;

FIGURE 1C illustrates the final phase of this prior-art sequence wherein a femoral prosthesis is inserted into the injected cement prior to hardening;

FIGURE 2A illustrates a prior-art improvement over the sequence shown in Figures

1A through 1C, wherein a distal plug is used for distal centering of the implant;

FIGURE 2B illustrates yet another prior-art improvement over the approach of Figure 2A wherein a vertically oriented rod is attached to the distal plug over which an implant may be slid after cement injection to further inhibit movement during curing;

5       FIGURE 3 is an arrangement according to this invention showing the use of a proximal cap which may be used either with a specially prepared prosthetic device or commercially available unit; and

FIGURE 4 illustrates two independently usable alternative embodiments according to the invention, including a multiple degree-of-freedom proximal retainment structure and a  
10       distal plug including leaf springs.

#### Detailed Description of the Preferred Embodiments

Figure 1 of U.S. Patent 5,340,362 shows an existing, prior-art procedure for inserting and cementing a prosthesis into a bone cavity, and this figure has been reproduced herein. In accordance with this technique, the canal is reamed or broached as shown in Figure 1A, and  
15       a trial is typically inserted therein to ensure that the final prosthetic component will be properly received. After this trialing, cement is injected into the excavated area as shown in Figure 1B, and the prosthesis is inserted as shown in Figure 1C, and left in position while the cement hardens. As discussed in the background of the instant invention, the technique just described is deficient in that, although the prosthesis may be optimally oriented during the  
20       trial procedure, the position of the actual implant may shift upon insertion into the cemented host or thereafter, resulting in a misaligned final fixation.

Various improvements also exist in the prior art to minimize such adjustment problems. At the very least, as shown in Figure 6 of U.S. Patent 4,994,085, reproduced herein as Figure 2A, a distal centralizer 16 is inserted beforehand into the intramedullary  
25       cavity 13 to which the distal tip 17a of the implant 17 engages at point 16a. This, at least, stabilizes the relative position of the distal tip 17a, resulting in a narrower range of angles (A

to B) through which the implant 17 may move within the cement-filled cavity prior to final curing. The teachings of this reference further improve upon post-cementation stabilization by incorporating a stabilizing rod 4 into the distal plug 6 over which a specially designed implant 2 having a centralized hole 4 is slidably installed, as shown in Figure 2B herein  
5 (Figure 4 of the issued patent). Assuming the various connections between rod 5, plug 6 and the inner walls of the intermedullary canal are relatively rigid, and the various tolerances involved are substantially tight, movement of the implant 2 is further restricted until the cement finally cures.

Another approach taken according to the prior art involves the injection of cement  
10 after positioning of a specially designed implant into a prepared cavity. The '362 patent referenced above is directed toward such an approach. As with other arrangements of type, the final implant includes a cement canal along its longitudinal axis. A bone-cement injector is threaded onto the proximal portion of this cement canal, causing the cement to subsequently travel down and through the implant, eventually exiting through openings in  
15 and around its distal tip. A restrictor plug halts downward cement travel, thus initiating an upward, retrograde filling of the void in between the prosthesis and the cancellous bone wall. In addition to a single distal aperture through which the injected cement is introduced, side ports may also be included, as shown in U.S. Patent 4,274,163 and various other prior-art references.

20 The methods and associated apparatus just described exhibit various shortcomings. In the technique described with reference to Figure 2B herein, although movements within the curing cement bed are further restricted, the point of substantial stability remains at the distal tip of the implant, enabling a certain level of proximal misalignment to continue, as no true proximal stabilization is provided. Worse, perhaps, is that since the centering rod and  
25 bore through the specialized component are both circular, the final implant is still subject to up-and-down and/or rotational variation, resulting in potential misalignment upon fixation.

With respect to the techniques wherein cement is injected after installation, although

the implant may be stabilized both proximally and distally as the cement is injected, as with the device of the '085 patent, a specially designed implant including the injector ports must be utilized, resulting in a specialized unit demanding significantly higher cost. Furthermore, regardless of the existing system utilized, attention to the pressure of the cement during injection and curing has not been adequately addressed. Although, for example, the system described in the '163 patent referenced above utilizes various components to maintain pressurization, numerous sophisticated articles are required, including a high pressure nitrogen gas source, disposable cylinder and various associated valves and tubing which may be difficult to assemble, require skilled operators, or create expensive waste and maintenance problems.

The present invention improves upon the prior art by providing a simplified apparatus and associated installation methods whereby an implant may be oriented both proximally and distally prior to the injection of cement, while, at the same time, providing means for guarding against rotational and up/down movement of the implant as well during such injection and subsequent curing. In addition, configurations according to the invention provide a simple means for expelling over-pressurized cement, thereby yielding a simple, but satisfactory indication that sufficient cement has been injected to an acceptable level. Although, in one embodiment, the invention makes advantageous use of a longitudinal bore through the implant, in another embodiment, all of the above improvements and advantages are realized in conjunction with standard, currently available prostheses, thus resulting in an approach which is both straightforward and economical.

Figure 3 is an oblique drawing of an arrangement according to this invention depicting various independent embodiments. Overall, an implant 310 is shown inserted into a prepared cavity 312, in this case the implant 310 being a femoral hip prosthesis and the cavity 312 being the intramedullary canal, though, as will be apparent to those of skill in the art of orthopedics, the general principles disclosed herein are not restricted to this application, and may be used in other joint situations, including the knee, shoulder and other

situations. Certain features of the femur are shown such as the greater trochanter 313 and lesser trochanter 315, and it is assumed that a resection not visible in this figure has been performed on at least a portion of the proximal end of the femur along with reaming and other preparation of the medullary canal itself to accept the implant 310.

5 Broadly, according to the invention, an apertured proximal sealing cap is installed over the resection portion of the femoral shaft, the prosthesis 310 is inserted through the proximal opening 320 of the seal, and cement is injected through an injection port 322. In a preferred embodiment, this proximal seal includes a horseshoe-shaped collar 330 having one or more means such as thumb screws 332 for releasably securing the collar 330 over the  
10 bone, and a preferably pliable gasket 334 made from rubber or other suitable polymeric materials through which the aperture 320 is formed. Also located on and through this gasket 334 is a flap valve 336 wherein the material forming the gasket 334 is adjusted to flap open or rupture at a predetermined pressure level, preferably on the order of 25 mm of mercury, which has shown to be advantageous for such orthopedic purposes. Preferably, this flap  
15 valve 336 is formed either by scoring the material of the gasket 334 in a manner conducive to such rupture, or, alternatively, the material may be thinned in this area to break under load.

The embodiment of the proximal seal just described is that preferred for use in conjunction with standard, commercially available implants. That is, the aperture 320 formed in the gasket 334 may take the form of a slit, an oval, or another shape appropriate to  
20 the stem of the implant, enabling the device to be inserted therethrough and retained in place by the surrounding material of the gasket 334 against the stem, either through friction or high-tolerance. Alternatively, then, if a more precise geometry of the stem at the point where it emerges through the proximal seal is known, the material 334 may be of a more rigid composition, and may, in fact, be integrally formed to the collar 330, in which case the  
25 injection port 322 and valve 336 may be more elaborate and substantial. For example, if the area 334 is metal, the port 322 may be threaded for a more solid connection to commercially available injector nozzles, and the valve 336 may take advantage of more sophisticated

pressure-release techniques available in the art, including adjustability for a particular pressure or range of pressures.

Whether the implant is of a standard configuration or specialized for use in conjunction with the invention, a distal spacer 340 is preferably utilized for distal centering.

5 A longitudinal rod 342 may optionally be added to, or installed on the plug 340, requiring a specialized implant having a longitudinal bore 344 akin to that described in the '085 patent referred to above, the exception being that, according to this invention, the implant 310 would be monorailed onto the optional rod 342 prior to the injection of cement into the cavity formed between the walls of the implant and the prepared medullary canal. Thus, as

10 discussed above, the present invention may either be used with a specially prepared implant having this longitudinal bore and/or convenient wall geometries or, alternatively, and unlike the prior art, a standard prosthesis may be used.

In the event that the prosthesis includes an arrangement to assist in installation or removal such as ring 350, the alternative proximal stabilization configuration of Figure 4

15 may be used. To further assist in proximal securement, a multiple degree-of-freedom clamp arrangement illustrated generally at 404 may be attached to a proximal cover 406 secured to femoral end or attached to a portion of available bone material by whatever means. In the embodiment shown, a first rod 408 securely affixed to the member 406 at point 409, onto which there is disposed a slidable collar 412 which may be locked into position with a

20 suitable device such as thumb screw 414. A second rod 420 and collar 422 contains two thumb screws, one to lock the collar 422 in position along rod 420, and a different thumb screw 430 for positive engagement with the prosthesis proper. It will be understood to those of skill that various other approaches may be utilized in accordance with the general principle contained herein to grasp and hold any portion or aperture of a standard implant

25 without requiring its modification.

Figure 4 also shows an alternative distal plug according to the invention which may be used in combination with any of the embodiments previously described. With such an



inventive plug, it is first seated distally at an appropriate distance within the intermedullary canal, and includes a plurality of deformable upwardly oriented leaf springs 490. Accordingly, with the plug 480 installed in place as shown, an even more generalized type of implant, and not requiring an actual, solid connection to such a distal spacer, may be inserted  
5 down and into the medullary canal and held in place while resisting distal side-to-side motion as the distal tip of the implant is retained within these leaf springs 490. This also allows adjustments in a longitudinal direction enabling fine tuning at the effective length of the implant. Note in Figure 4 that the aperture through which the implant is inserted is quite a bit larger than that shown in Figure 4 and, in fact, does not include a seal per se. This is  
10 due to the fact that, in accordance with this embodiment, cement may, in fact, be injected prior to or after the implant is held in place both proximally and distally. Indeed, according to this particular embodiment, a standard distal plug may be used in conjunction with the mechanism shown generally at 404 even without a cap or collar as shown. For example, this mechanism 404 may simply attach to an existing bone surface or structure instead of the  
15 point 409, thereby holding the implant in place proximally and distally while preventing motion in all dimensions as the cement cures, regardless of when it was injected. In accordance with an alternative methodology, the proximal and distal stabilizers may be used in conjunction with a trial then, upon achieving a desired orientation, a single manual fastener may be loosened, and the actual implant installed in the exact configuration of the  
20 trial to guarantee proper positioning.

I claim: